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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 485,245	03 27 2000	ALISON HOPKINS	28911 36128	1697

7590 11 27 2002  
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EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11 27 2002

*Handwritten signature/initials*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/485,245

Applicant(s)  
Hopkins, A

Examiner  
Cynthia B Wilder

Art Unit  
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 6, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-6 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/6/2002 has been entered. Claims 1, 3-6 are pending.

### ***Declaration***

2. The declaration submitted under 37 CFR 1.132 filed 11/6/2002 is insufficient to overcome the rejection of claims 1-6 based upon the prior art rejections under 35 U.S.C. 103(a) as set forth in the last Office action because the facts presented are not germane to the rejection at issue. The Experts discussion of the buffers as utilized in the experiments presented in the specification is acknowledged. However, the prior art rejections are not based on the criticality of the buffer solution to the instant invention. The prior art rejections are based on the fact that the claims as written encompass a labeling composition comprising a random mixture of oligonucleotides which are 6-mers. The use of random 6-mers as a labeling composition are well known in the prior art as discussed in the prior Office Action. The buffer solution as discussed by the Expert does not provide any unexpected results of the labeling composition over the prior art or present any new discover for the action of the labeling composition over the prior art. The claims as written broadly encompasses a random mixture of oligonucleotides that are 6-mers **or** a random mixture of oligonucleotide that

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are 7-mers **or** a random mixture of oligonucleotides that are 8-mers **or** a combination therein. In this case, as noted in the prior Office action, the prior art (Godiska et al) teaches a labeling composition comprising a random mixture of oligonucleotides that are 6-mers. Godiska et al. further teach wherein the composition further contains at least a supply of nucleotide for chain extension, a labeled nucleotide, and a polymerase enzyme. The reference does not teach the labeling composition in a dried state. This limitation however is found in the secondary reference of Shen. Shen teaches a composition comprising primers, a polymerase enzyme, a supply of nucleotides for chain extension and a stabilizer which are all present in a dried state. Shen provides motivation for wanting a composition in a dried state in the teaching that "a composition in a dried state is advantageous because the composition is stable for a prolonged period, even when stored at high temperatures". The reference provides further motivation in the teaching that a composition in a dried state is useful in shipping and storage of commercial preparations for use in e.g., nucleic acid amplification. To reiterate, the arguments are not sufficient to overcome the prior art rejections. Accordingly the rejections are maintained.

***Claim Rejections - 35 USC § 103***

3. Claims 1, 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godiska et al. (5,759,804, filed November 17, 1993) in view of Shen et al. (EP 0 726 310 A1 February 09, 1996). Regarding claims 1, 3 and 4, Godiska et al teach a labeling composition comprising a random mixture of oligonucleotides which are 6-mers, wherein the composition further contains at least a

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supply of nucleotides for chain extension, a labeled nucleotide, and a polymerase enzyme (col. 8, lines 27-31). The labeling composition of Godiska et al differs from the instant invention in that Godiska et al do not expressly teach wherein the labeling composition is in a dry state. Shen et al teach a composition similar to that of Godiska et al present in a dry state (page 4, lines 37-41). Shen et al teach wherein the composition may comprise primers, a polymerase enzyme, a supply of nucleotides for chain extension, and a stabilizer (page 6, lines 3-7 and 22). Shen et al teach that the composition present in the dry state is advantageous because the composition is stable for a prolonged period, even when stored at high temperature. Shen et al further teach that a composition in a dried state is useful in shipping and storage of commercial preparations for use in e.g., nucleic acid amplification kits (page 6, lines 39-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have been motivated to provide the labeling composition as taught by Godiska et al in a dried state for the advantage taught by Shen et al that a nucleic acid composition present in a dried state is useful in shipping and storage of commercial preparations due its increase stability.

Regarding claim 5, Godiska et al teach a method of making a labeled probe for a nucleic acid template, wherein the method comprises the steps of providing a nucleic acid template and a labeling composition and incubating the nucleic acid template under chain extension conditions with the labeling composition to produce a labeled probe (col. 8, lines 27-31).

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Godiska et al. in view of Shen et al. and further in view of Hoeltke et al. (5,814,502, effective filing date October 1994).

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Regarding claim 6, Godiska et al in view of Shen et al teach a labeling composition and method of making a labeled probe comprising a number of method steps wherein the labeled compositions comprises a random mixture of oligonucleotides which are 6-mers and said composition present in a dry state. The labeling composition of the disclosure differs from that of the references in that the references do not expressly teach the concentration of the random mixture of oligonucleotides. However the optimal contents range would have been determined by the practitioner based on desired properties of the random oligonucleotides, desired lengths of the random oligonucleotides and desired results. For example, in a method for labeling nucleic acid, Hoeltke et al teach a random mixture of oligonucleotides wherein the concentration range of approximately 15 to 80 OD/ml is selected for the various random primers which are 6-mers to 15- mers. Hoeltke et al further teach that depending on the primer length, the optimal contents range will change (col. 2, lines 55-60 and col. 3, lines 38-42). Therefore, in view of the foregoing, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made that the concentration range of the random mixture of oligonucleotides is variable based the practitioner's preference as well as the length of the primers as suggested by Hoeltke et al.

### ***Conclusion***

5. No claims are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The

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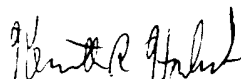
examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

November 21, 2002

  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

11/25/02